UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,388	11/28/2000	Jin Hong	7682-051-999	8169

20583 7590 12/28/2004

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,388	HONG ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,12-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *9, 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,10,12,17,18 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-15-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 7-10, 12-18, and 20-22 are pending in the application.

2. In the prior action, mailed on June 15, 2004, claims 7-21 were pending, with claims 7, 8, 10-12, 17, 18, 20, and 21 rejected; and claims 9, 13-16, and 19 withdrawn as to non-elected inventions. In the Response filed on October 15, 2004, the Applicant amended claims 12, 18, and 21; and added new claim 22; and cancelled claims 11 and 19. Claims 7, 8, 10-12, 17, 18, 20, 21, and 22 are under consideration to the extent that they read on the elected subject matter, or are generic thereto. Claims 9 and13-16 are withdrawn as to non-elected inventions.

3. It is noted that the Applicant asserts that claim 19 should be examined with the elected inventions. However, as this claim has been cancelled from the Application, the argument is moot.

4. Because this action raises issues not raised in the prior action, it is being made Non-Final.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on October 15, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

6. It is noted that three of the references cited in the October 2004 IDS have been crossed out in the reference listing. This is because these references were previously considered and made of record in the PTO Form 892 mailed with the office action of June 15, 2004.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claim 12 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim reads on a vaccine comprising a genetically manipulated virus of the paramyxoviridae family, wherein the genetic manipulation comprises any insertion, deletion, or substitution, and may also, optionally, comprise a heterologous sequence. The viruses of the paramyoviridae family are further identified in the dependent claims as including the parainfluenza virus (PIV) and RSV. Thus, while the claims are broadly drawn to vaccines against any non-segmented, negative-stranded RNA virus, or to any paraxymovirus, the contents of the specification, and the dependant claims clearly indicate that the presently claimed invention is focused on vaccines against RSV. The Applicant has added new claim 20 to the application, which also reads on such anti-RSV vaccines. The rejection is therefore extended to this claim.

The Applicant provides four arguments in traversal. First, the Applicant asserts that chimpanzees are an accepted animal model for the efficacy of RSV vaccines in humans, and that such models have shown protection against the virus in the models. The Applicant further argues that the problems associated with RSV vaccination have been overcome by the teachings of the

present application. Third, the Applicant argues that the Examiner has applied the wrong standard to the present case. Applicant argues that, while the rejection is an enablement rejection, "the gravamen of the Examiner's rejection is that the claims compositions lack utility as vaccines." Finally, the Applicant notes that in the prior action, the Examiner found the Applicants arguments that the arguments based on animal models were not found persuasive because the art teaches that there is not art-accepted models for testing RSV vaccines, and argues that the Federal Circuit has held that testing the safety and efficacy of vaccines is left to the FDA, and not within the purview of the Patent Office.

These arguments are not found persuasive.

The first and fourth arguments are related. The first argument is not found persuasive because, as with the Green Monkey model referred to previously, the art has known of the models, and has effectively produced protection in them, but have nonetheless failed to provide an effective vaccine for human use. See e.g., Dudas et al., Pages 435 (teaching the use of the chimpanzee model) and 430 (teaching that despite the use of animal models referred to later in the paper, those in the art have been unable to produce a safe and effective vaccine for humans). As a whole, the art does not support the Applicant's implicit assertion that a showing of effectiveness in this model provides anything more than relevant information relevant to the effect of recombinant RSV in humans. Rather, while the art uses such models to provide information, the art also indicates "the level of attenuation for these viruses can only be determined definitively in human studies." Crowe et al., Virus Res 59: 13-22, at page 20. Thus, the efficacy of a particular virus in chimps does not demonstrate vaccine efficacy in humans.

The Applicant notes that the teachings in the cited Teng reference indicate that "the compositions of the invention" were shown to be effective in chimpanzees. The Applicant then refers attention to MPEP § 2164.02 which states "if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate," to assert that the reference demonstrates that the claimed invention has been enabled. However, in addition to the teachings above that the animal model is not sufficient to demonstrate efficacy of the composition as a vaccine, Teng itself indicates that the showings in chimps do not directly carry over to humans. In particular, on page 9320 of the reference, Teng states that the virus tested in the chimps was both insufficiently attenuated, and overattentuated for the two primary target populations of human vaccination. Thus, this reference itself both states and demonstrates that the results achieved in chimps do not correlate to the results that would be achieved in humans.

In addition to these teachings, Teng also provides teachings relevant to the predictability of the art of RSV vaccination. Teng teaches that the compositions tested in the reference were not just any attenuated RSV vaccine with any random genetic alteration. The reference teaches that the virus used in the reference was a compilation of several mutations, each of which appears to have been independently identified. Pages 9317, and 9319 (describing the methods of identifying attenuating mutations both through biological means and recombinant experimentation). The reference re-emphasizes the teachings in the art previously cited regarding the difficulty in balancing the attenuation and the immunogenicity of the mutants. Thus, the reference simultaneously teaches that the art involves a good deal of unpredictability, and the identification of effective mutants involves a great deal of experimentation, and that not every

virus that falls within the scope of the claims would be capable of providing an effective vaccine against infection.

The teachings of Teng support the Examiners conclusions made from the references cited in the prior action. These references, either individually or cumulatively, demonstrate or describe the unpredictability in the art, and demonstrate that a large amount of experimentation would be required, even with the teachings of the present application, to develop an effective RSV vaccine. Thus, the Applicant's arguments relating to the use of the chimpanzee models is found unpersuasive for the same reasons as indicated previously with respect to the other animal models. The first argument in traversal is therefore not found persuasive.

It is noted that the safety and efficacy of drugs is, as asserted by the Applicant, within the purview of the FDA, and not the Patent Office. However, while this may be the case, this does not preclude the Office from finding that the Applicant has not provided sufficient enabling support for a claimed invention. As is noted in the MPEP 2164.05, "considerations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled." In the present case, the Applicant is claiming a broad class of mutated RSV for use in vaccines. However, those in the art, although they have known how to make mutated RSV, have been unable to produce such vaccines that are safe and effective in humans. Thus, while the safety and efficacy of the RSV is within the purview of the FDA, the Office may take note that the art indicates that these characteristics are also found to be unpredictable with reference to human use. Thus, while the Office may not determine whether a specific is safe and effective for human use, in cases where the art provides evidence that the Applicant may not be enabled for such use, and where the Applicant has provided no evidence to

the contrary, the Office may question whether the Applicant has provided sufficient information to enable those in the art to use the claimed compositions for the intended use. Thus, the Applicants fourth argument is also not found persuasive.

The second argument, that the presently claimed invention overcomes the uncertainty in the prior art is also not found persuasive. In support of the assertion that they have overcome the problems in the prior art, the Applicant looks to the results in animal models. However, as was indicated above, and in the prior actions, such is not sufficient to demonstrate that the claimed inventions have overcome the unpredictability in the art with respect to human use. In particular, the art indicates that there is difficulty in moving from protection in animals to protection in humans. Thus, the art also indicates that, despite the use of such models, the development of a safe and effective human vaccine has so far eluded those in the art, and the adaptation of the vaccines to humans requires more than routine experimentation. For these reasons, and the reasons of record, the Applicant's arguments in traversal are not found persuasive.

The third argument presented by the Applicant, that the Examiner has applied the wrong standard in this enablement rejection, is also found unpersuasive. As indicated above, the Applicant argues that while the claims are rejected for lack of enablement, the rejection is, in essence, a utility rejection. They argue that, due to this, the case is comparable to the decision by the Federal Circuit in In re Brana (34 U.S.P.Q. 2d 1437, 1995), which overturned an enablement rejection based on inoperability because the Office had not established that the rejected claims did were not inoperable under the 35 U.S.C. 101 utility standard for inoperability. The Applicant therefore concludes that where the Examiner bases an enablement rejection on inoperability, the

appropriate standard for determining the issue is that provided for inoperability under 35 U.S.C. 101. This argument is not found persuasive.

The situation in Brana is not identical to the present application. In this case, the claims have been rejected because the Applicant has not established that those in the art could make or use a vaccine against RSV based on teachings in the application without undue experimentation. The Examiner has not asserted that no attenuated virus could be used as a vaccine, as would be the case in a situation relevant to Brana. Rather, the rejection is based on part on the assertion that the teachings in the art do not support the Applicants argument that efficacy of a virus in protecting a chimpanzee is sufficient to demonstrate efficacy in a human. The Examiner agrees with the Applicant that there is no basis in the art to believe that an attenuated virus would be "totally incapable of achieving a useful result." However, the Examiner does not agree that, based on the teachings of the art and of the application, the Applicant has enabled those in the art to make and/or use an attenuated RSV as a vaccine against RSV infection. These are separate issues.

As was indicated above, the issue surrounding the animal models of RSV infection is whether those in the art would accept such as demonstrating that a particular attenuated virus would be an effective anti-RSV vaccine. For the reasons provided above, the Examiner has concluded that the art has not established that efficacy in chimps is predictive of efficacy in humans. The Examiner has not concluded that anything is inoperable, but only that the animal model does not demonstrate vaccine efficacy in humans. This conclusion does not, however, rise to the point of questioning the ability of any attenuated virus to act as a vaccine. Rather, this conclusion is merely a factor (state of the art, and/or presence of working examples) considered

in determining if the application has provided sufficient information such that those in the art would be able to make or use the claimed RSV variants as a vaccine composition without having to perform undue experimentation.

For these reasons, and the reasons of record, the Applicant's arguments in traversal of the rejection are found unpersuasive, and the rejection is maintained.

9. **(Prior Rejection- Maintained)** Claims 7, 8, 10-12, 17, 18, 20, and 21 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims have been amended to read on genetically manipulated replication competent infectious RSV comprising any insertion or deletion, or any insertion, substitution, or deletion of an entire open reading frame (ORF). Claim 11 has been deleted from the application. However, claim 22 has been added. The rejection is therefore withdrawn from cancelled claim 11, but extended to new claim 22.

The Applicant traverses this rejection by arguing that those in the art would be able to "easily determine" if a given virus met the functional limitations of the claims. The Applicant also cites the decision by the CCPA in In re Angstadt (190 U.S.P.Q. 214, CCPA 1976) stating that the Applicant need only provide sufficient information to enable those in the art "to determine, which reasonable certainty before performing a reaction whether the claimed product will be obtained..." The Applicant asserts that such guidance towards operative embodiments has been provided. This argument is not found persuasive.

As was noted in the prior action, the claims are drawn to any replication competent, infectious RSV comprising any addition or deletion; or any addition, substitution, or deletion of an entire open reading frame (ORF). However, the Applicant has provided examples of only a few of the claimed modifications; of these, some were operative, others were not. Among those examples, there is no obvious correlation between the structures or types of modifications made and their operability, or inoperability. Thus, those in the art would have no or little certainty in the operation of any given embodiment prior to their attempts to make or use it.

While the Angstadt court indicated that the Applicant need not describe every potential embodiment of the claimed invention to demonstrate enablement, the court does require a "reasonable certainty" in the practice of the claimed invention. In that case, the issue related to the ability of particular catalysts to be used in a claimed method to achieve a desired product. The claims were directed to the use of a particular class of catalysts, of which a large number of examples had been provided, one of which was inoperative. In view of the identification of the class of catalysts useful in the claimed method, and the large number of operative examples provided, the court determined that the Applicant in that case had provided sufficient information such that those in the art would be able to easily determine which catalysts did or did not fall within the scope of the claimed inventions. While related in some aspects to the present case, the Examiner does not find that the argument based on Angstadt demonstrates that the Applicant is enabled for the presently claimed genus of inventions.

Unlike the case in Angstadt, where the catalysts were functionally and structurally related, the present claims are not directed to a particular group of functionally or structurally related modifications to the viral genome. In addition, unlike in the Angstadt case where only

one of the many examples proved to be inoperative, in the present case, in the present case the Applicant notes that seven (of an undefined number) of embodiments were inoperative. Additionally, the Applicant does not identify the tested operative or inoperative embodiments (see e.g., pages 57-59), such that these teachings are not useful to those in the art in determining which other embodiments may or may not fall within the claim scope. Thus, the fact pattern of the Angstadt case does not match that of the current application in at least two important aspects.

Additionally, while the decision of Angstadt indicates that applicants "are not required to disclose every species encompassed by their claims, even in an unpredictable art," later decisions have stated:

> However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element.

In re Vaeck, 20 U.S.P.Q. 2d 1438, at 1445 (Fed Cir 1991). As was indicated above, where the Angstadt case related to a defined set of catalysts, the present application claims any mutation within the RSV genome. There is no common factor among the claimed modifications other than the result, and the fact that they were made to the RSV genome. In short, aside from providing little guidance to other operative embodiments, it is not clear that the disclosed operative embodiments provide a representative sample for the full scope of the claimed modified RSV. For these reasons, and the reasons of record, the Applicant's arguments in traversal are not found persuasive. The rejection is therefore maintained.

With respect to claim 21, it is noted that this claim has been amended to read on modifications to the M2-2ORF, rather than to the M2 ORF in general. In view of this, the additional grounds of rejection applied against this claim appear moot. However, the rejection of the claim is maintained for the reasons applied to the claims generally above.

10. **(Prior Rejection- Maintained)** Claims 7, 8, 10-12, 17, 18, and 20 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant traverses the rejection by asserting that they have provided sufficient description of non-segmented negative stranded DNA viruses by providing a means of rescuing such viruses from cloned DNA, and suggesting types of mutations that may be made. This argument is not found persuasive. The rejection is therefore maintained against pending claims 7, 8, 10-12, 17, 18, and 20, and extended to new claim 22.

The Applicant's statement of the requirements for providing written description support appears to be correct. However, contrary to the Applicant's assertions, the Examiner does not find that the Applicant has met either of the two suggested modes of providing support for the claimed genus. These two modes are 1) through providing a representative number of species of the full scope of the claimed invention, or 2) by providing identifying characteristics of the claimed inventions. In the present case, while the Applicant has provided both a number of examples, and has identified both a functional and structural identification of the claimed

invention, these disclosures to not provide adequate support for full scope of the claimed inventions.

First, with reference to the provision of a representative number of species, it is noted that each of the examples provided by the Applicant relate to RSV viruses, the genome of which is known to vary from the genomes of the other paramyxoviruses, and other negative strand viruses. Thus, it is not clear that the disclosed embodiments of the claimed invention would be representative of any of the claimed virus because the Applicant has demonstrated possession of only mutated forms of only a single species of virus. Additionally, as was indicated both above, and in the prior actions, while the Applicant has provides examples of modified RSV, the examples provided do not appear representative of the full scope of the claimed inventions. The claims are drawn to any modification within the viral genome that results in a replication competent and infectious virus. However, the Applicant has shown examples of modifications in only some of the structural regions of the RSV viral genome, and has not shown how these disclosed operative embodiments provide any information as to the possession of mutations in other regions of the genome. Thus, the Applicant has not shown a representative number of examples.

This conclusion finds further support in the decisions regarding written description which state that even the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) ("where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a

patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support). In the present case, as was noted previously, the teachings of the present application as well as those in the art each indicate that there is great unpredictability with reference to the performance of any particular species within the claimed genus of inventions. While the Applicant does point to particular protein encoding sequences in which mutations may be made, the teachings of both the Application and the art indicate that mutations in these sequences still maintain the uncertainty found in the modification of the genome in general. Thus, the Applicant has not provided a sufficient number of operative examples to demonstrate possession of any operative mutant virus.

With respect to the identification of functional/physical characteristics, it is noted that although the Applicant has provided both a functional (replicating and infectious) requirement and a physical requirement (mutations to the viral genome) there is no correlation between the two as is required when a functional characteristic is relied upon. See, Eli Lilly, 43 U.S.P.Q. 2d at 1406 (quoted in the prior action). As has been shown by the Applicant (e.g. pages 57-59, and 62 and 63), different mutations, even within the same protein encoding sequence, can result in virus with different characteristics; some of which fall within the scope of the claims, and others that do not. In view of the lack of correlation between the identified structures and functions, and the uncertainty as to whether any particular RSV genome mutation would result in a virus according to the claimed invention, the Applicant has not provided sufficient written support for the claims under the second of the indicated means of providing support.

Because the Applicant has not established that the disclosed embodiments are 1) representative of any genetically manipulated, replication competent, and infections

paramyxovirus, or RSV, or 2) that the provided identifying functional characteristics have any correlation with the provided structural characteristics, the Applicant's arguments are not found persuasive. The rejection is therefore maintained for the reasons above, and the reasons of record.

11. **(Prior Rejection- Withdrawn)** Claims 21 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim has been amended to read on a modified member of the paramyxovirus family, wherein the modification entails an insertion, substitution, or deletion of the M2-2 protein. In view of the amendment of the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

12. **(Prior Rejection- Withdrawn)** Claim 11 was rejected under 35 U.S.C. 102(a) as being anticipated by either of Conzelmann et al, J Virol. 68(2): 713-19, or Schnell et al., The EMBO Journal 13(18): 4195-4203 (September 15, 1994- of record in the March 2, 2001 IDS). The claim has been amended to read on a genetically manipulated member of the paramyxoviridae family. Because the Conzelmann and Schnell references relate to the Rabies virus, which is not a member of the paramyxoviridae family, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **(New Rejection)** Claim 18, and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al., U.S. Patent 5,993,824 (of record in the action mailed on September 24, 2003). These claims read on genetically manipulated RSV wherein an ORF encoding a viral gene product has been inserted, deleted, or a substituted. Claim 21 has been amended such that, instead of reading on a deletion, insertion, or substitution of the entire M2 ORF, the claim reads on a virus comprising the insertion, deletion, or substitution of the M2-2 ORF. While the Applicant has support for the insertion, deletion, or substitution of the M2-2 ORF of RSV in the parent application 09/161,122, there does not appear to be support for the embodiment of claim 21 in application 08/316,439 (now U.S. Patent 5,840,520). Nor does the 08/316,439 application appear to provide support for any substitution or deletion of any RSV ORF. Thus, the Applicant is not accorded priority of the indicated claims to the 08/316,439 application.

The Murphy patent teaches that the genes for target proteins of RSV may be substituted or deleted in the recombinant virus made according to the disclosure. See e.g., columns 5-6. Additionally, the reference indicates that the M2-2 protein is not required for viral replication, and actually hinders replication of the virus. See e.g., columns 84-85. It would therefore have been obvious to those in the art to produce RSV comprising a deletion of the M2-2 gene so as to

provide for the necessity of the M2-1 gene, but to avoid the loss of replication due to inclusion of M2-2 inhibitory activity. The teachings of the indicated reference therefore render the claimed invention obvious.

Conclusion

15. No claims are allowed.

16. Applicant's statement regarding U.S. Patent 6,033,886 to another applicant is noted. However, because the patent is issued from a different application, it is not clear what relevance the issue of that patent has on the patentability of the present claims to the current applicants.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 12/26/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600